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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT PAPER NUMBER

1617

DATE MAILED: 08/12/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/991,283	FARBER, ELLIOTT
	Examiner Shahnam Sharreh	Art Unit 1617

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 27 May 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-173 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) _____ is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) 1-173 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. _____.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____

4) Interview Summary (PTO-413) Paper No(s). _____

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____

Election/Restrictions

1. Applicant's election of species filed on May 27, 2003 has been fully considered. However, the response was non-responsive because first, no single species or a single compound was elected as the emulsifier; and second, no election was made for a single species of the therapeutic agent and the skin conditions. Accordingly, Examiner hereby clarifies the earlier requirement made to facilitate expeditious prosecution of the claimed invention.
2. Claims 1-173 are drawn in Markush format, and contain multiple independent and patentably distinct inventions. The invention is primarily directed to methods of treating various etiologically distinct skin conditions employing allantoin and various types of emulsifying systems and therapeutic agents. Therefore, a requirement to provisionally elect a single species is made as provided in MPEP § 803.02.
3. This application contains the following patentably distinct species:
 - Various emulsifying systems selected from the following groups:
 - a) Acidic wax such as beeswax and anionic emulsifiers (claims 1-21, 137-150, 159-173) classified in class 514, subclass 942 or class 424, subclass 70.22.
 - b) Non-ionic emulsifiers that are ethoxylated ethers (claims 22-34 in-part, 60-70 in-part, 110-122) classified in class 514, subclass 943.

- c) Non-ionic emulsifiers that are ethoxylated esters (claims 22-34 in-part, 35-48, 60-70 in-part, 123-136, 151-158), classified in class 424, 70.31.
- d) Acidic anionic polymers and anionic emulsifiers (claims 49-59), classified in class 424, subclass 70.22 or class 514, subclass 937.
- e) Acidic anionic polymers (claims 71-83), class 424, subclass 70.11.
- f) Cetyl alcohol and stearic acid (claims 84-96), classified in class 514, subclass 553+ or 938.
- g) Sodium stearoyl lactate and sodium isostearoyl lactylate (claims 96-109) classified in class 424, subclass 400.
- h) carbohydrate polymers, acidic wax, and anionic emulsifier (claims 137-150, 159-173), classified in class 514, subclass 54+.

Applicant's attention is also drawn to claims 151-158 where they depend on claim 126, which respectively does not require anionic emulsifiers as a limitation. However, the element (c) of claim 151-158 limits the claims to an anionic emulsifier. Clarification of such dependency is requested prior to election. Examiner believes that claims 151-158 should depend on claim 137 or any dependent claims thereof.

- Various therapeutic agents (claims 1-173), enumerated in claims 10, 33, 90 etc..

- Various skin conditions (claims 1-173), enumerated in claims 7, 30, 56, 87, etc...

4. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits from each of the bulleted species enumerated above, to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 22, 35, 49, 71, 84, 110, 123, 137 are generic.

5. Claims that are drafted in Markush-type format encompass patentably distinct species and are directed to multiple independent and patentably distinct inventions since the species are so unrelated and diverse that a reference anticipating one of the species would not anticipate or render obvious the other species. The species are considered to be independent when they are unrelated in operation, and one does not require the other for ultimate use, and specification does not disclose a dependent relationship between them. Further, each of the stated species is considered to be patentably distinct from the others on the basis of its properties.

6. For example, in the instant case, the emulsifying system of group (a) is unrelated in operation and properties when compared to the emulsifying system of group (f), because the components of each emulsifying system contain materially different compounds. Similar distinction exists among all other emulsifying systems.

7. Moreover, the instantly claimed species of skin condition are directed to various etiologically distinct diseases. For example, epidermolysis bullosa is a genetic anomaly, but pressure ulcers or decubitus ulcers are directed to such lesions caused by prolong external pressure on a local skin. Therefore, the claimed methods of treating such conditions differ in mode of operation and clinical effects because one can not render

obvious methods of treating decubitus ulcer over method of treating epidermolysis bullosa.

8. Similar analogies hold true for various species of therapeutic agents. Thus, the enumerated species are capable of supporting separate patents under 35 U.S.C. 121.

9. In the event that the Markush-type claims are not found to be allowable, the examination of the claims presented will be limited to the Markush-type claims to the extent that they read on the elected species and claims directed solely to the elected species. The claims directed solely to the non-elected species will be held withdrawn from consideration. A requirement to elect a species has been held to a tantamount to a requirement for restriction under 35 U.S.C. 121.

10. To properly respond to this election Applicant is advised to elect a single species from the groups of emulsifying systems and therapeutic agents enumerated above. For such species a single compound may be named in any of four ways (or any combination thereof): (a) according to the IUPAC standard, (b) by a pictorial representation of the compound, (c) by setting forth the specific chemical group that each variable of the Markush group represents, or (d) by naming a claim or an example which itself sets forth a single compound.

11. Applicant is also required to choose a skin condition if there exists any dependent claims directed to such conditions among the set of claims elected. For example if Applicant elects group (a) system containing anionic emulsifiers, a single compound must be identified as the elected species for the group anionic emulsifiers. Further, such election must accompany a skin condition from claim 7, and a therapeutic

agent from claim 10. Subsequently, the generic claims are examined to the extent that they read on the elected species, unless Applicant provides such evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. If the search for the elected species does not provide any applicable prior art, the search will be extended to the next compound until the entire scope of the Markush group is properly searched or at least one species is rejected.

12. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

13. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

14. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

16. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9306 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.



Shahnam Sharareh, PharmD
Patent Examiner, AU 1617